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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,990	10/30/2003	Jason A. Demers	1062/D85	7851

2101 7590 12/18/2006

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EXAMINER	
WEINSTEIN, LEONARD J	

ART UNIT	PAPER NUMBER
3746	

DATE MAILED: 12/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

mr

Office Action Summary	Application No.	Applicant(s)	
	10/696,990	DEMERS ET AL.	
	Examiner	Art Unit	
	Leonard J. Weinstein	3746	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/30/2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/30/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :7/29/04 7/18/05 12/25/05 9/14/06.

DETAILED ACTION

Information Disclosure Statement

1. Applicant should note that the large number of references in the attached IDSs' have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. See MPEP 609.05(b). Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 8, and 23-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Rosiello 7,011,742. Rosiello '742 teaches the invention as substantially claimed including an apparatus for use in a fluid processing workstation having a plurality of pumps, and further comprising: a plurality of pump cassettes 42 for use respectively with the plurality of pumps, 12 and 44, each cassette having a first fluid inlet port (comment #4 on Fig. 1) in selective fluid communication with a first pump chamber (comment #5 on Fig. 1), an inlet tube (comment #1 on Fig. 1), and distribution tubing (comment #3 on Fig.1) that connects the inlet tube to the

first fluid inlet port of each of the pump cassettes 42; an inlet tube centrally attached along the distribution tubing and the plurality of pump cassettes 42 are symmetrically attached to the distribution tubing with respect to the inlet tube attachment (comment #1 on Fig. 1); attachments of the plurality of pump cassettes 42 to the distribution tubing are equally spaced apart along the distribution tubing (comment #6 on Fig. 1); a plurality of incubation bags 32, each bag being attached to an outlet port on a respective one of the pump cassettes (comment #7 on Figure 1); a four-port coupling (comment #2 on Fig. 1) inserted in the distribution tubing such that the distribution tubing extends out from first and second oppositely located ports of the coupling, the first fluid inlet tube is connected to a third port of the coupling and the first fluid inlet port of a middle one of the pump cassettes is coupled to a fourth port of the coupling. Further Rosiello teaches a kit comprising a plurality of pump cassettes 40, each cassette 42 having a first fluid inlet port (comment #4 on Fig. 1) in selective fluid communication with a first pump chamber (comment #5 on Fig. 1), and an inlet tube (comment #1 on Fig. 1) and associated distribution tubing (comment #3 on Fig. 1) for connecting the inlet tube to the first fluid inlet port of each of the pump cassettes 42; and a plurality of incubation bags 32 for attachment respectively to an outlet port (comment #7 on Fig. 1) of each of the pump cassettes 42. Reference is made to Figure 1 of Rosiello, included subsequent to paragraph 2.

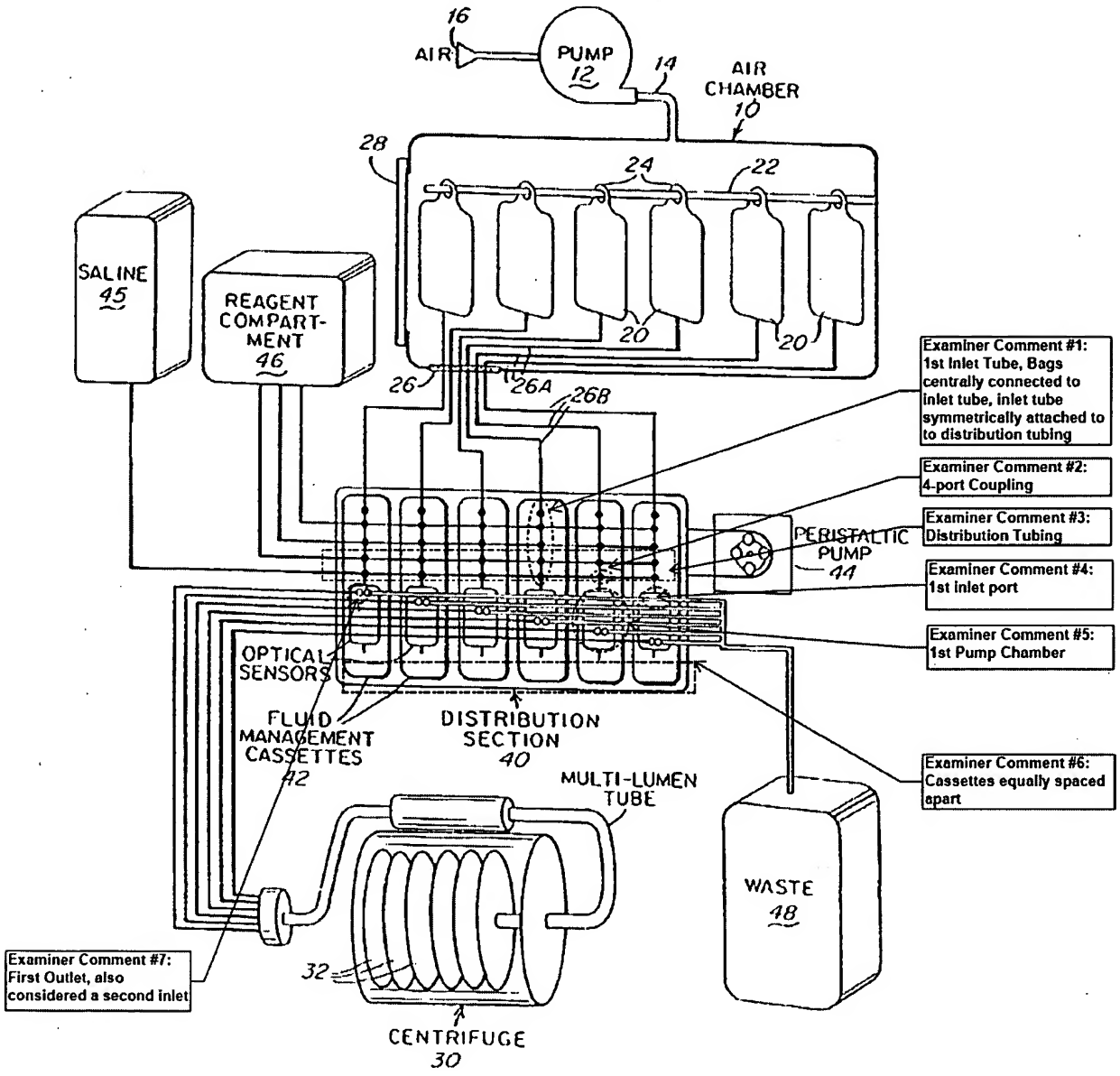
16
AIR
PUMP
12
14
AIR CHAMBER
10
28
24
22
SALINE
45
REAGENT COMPART-MENT
46
20
20
26
26A
26B
PERISTALTIC PUMP
44
OPTICAL SENSORS
FLUID MANAGEMENT CASSETTES
42
DISTRIBUTION SECTION
40
MULTI-LUMEN TUBE
WASTE
48
32
CENTRIFUGE
30
Examiner Comment #1: 1st Inlet Tube, Bags centrally connected to inlet tube, inlet tube symmetrically attached to to distribution tubing
Examiner Comment #2: 4-port Coupling
Examiner Comment #3: Distribution Tubing
Examiner Comment #4: 1st inlet port
Examiner Comment #5: 1st Pump Chamber
Examiner Comment #6: Cassettes equally spaced apart
Examiner Comment #7: First Outlet, also considered a second inlet

Fig. 1

4. Claims 9-11, 13, and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Dennehey et. al 5,482,440. Dennehey et. al '440 teaches the invention as substantially claimed including a pump cassette bank comprising: an odd number of pump cassettes, 22A, B, and C, each cassette having a working solution inlet port, T8 of element 22A and T9 of elements 22B and C, selectively coupled to a working solution pump chamber, F8 of element 22A and F9 of elements 22B and C, a working solution inlet tube 24 and distribution tubing, elements 64, 60, 76, and 86 of 18, connected between the working solution inlet tube and the working solution inlet ports of the odd number of pump cassettes, 22A, B, and C, wherein the working solution inlet tube joins the distribution tubing proximate to a junction 200 between the distribution tubing and a middle one of the pump cassettes 22B such that connected to the distribution tubing, 60 and 86, on either side of the junction 200 are an equal number of the pump cassettes, 22A and C; the pump cassettes connected to the distribution tubing on one side of the junction are spaced from the junction given distances from the junction and wherein at those given distances pump cassettes are connected to the distribution tubing on the other side of the junction with element 22B an equal distance from element 22A as from 22C; a plurality of incubation bags, 58, 90 , and 96, each bag being attached to an outlet port T1 on a respective one of the pump cassettes 22A, B, and C; a break-away closure 400 on the working solution inlet tube; each pump cassette 22A, B, and C includes a second fluid inlet port T3 with a second fluid inlet tube, 72, 92, and 78, attached thereto and further including a break-away closure 240 on the second fluid inlet tube. Further Dennehey teaches a plurality of pump cassettes 22A, B, and C, each pump cassette having a first inlet port, T8 of 22A and T9 of 22B and C, and an associated first pump chamber, F8 of 22A and F9 of 22B and C, a second inlet port T3 and an associated second pump chamber F3, an air vent and associated hydrophobic

filter (col. 20 ll. 39-55), an outlet port, a working solution inlet tube 24, distribution tubing 72, 92, and 78 of 22A, B, and C respectively, connected between the working solution inlet tube and the first inlet ports of each of the plurality of pump cassettes, elements 64, 60, 76, and 86 of 18, wherein the working solution inlet tube 24 is centrally connected to the distribution tubing such that there are an equal number of the pump cassettes, 22 A and C, connected to the working solution on either side of its junction with the distribution tubing; and the pump cassettes connected to the distribution tubing on one side of the junction are spaced from the junction given distances from the junction and wherein at those given distances pump cassettes are connected to the distribution tubing on the other side of the junction with element 22B an equal distance from element 22A as from 22C.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 9, 15-16, and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosiello 7,011,742 in view of Dennehey et al. 5,482,440. Rosiello '742

teaches the invention as substantially claimed and stated above but does not teach an odd number of cassettes having a 2nd set of inlet ports as is taught by Dennehey et al. '440 and stated above. The embodiment shown in Figure 7 of Rosiello shows a 1st set of blood containers 60 put under pressure by a pump 10A sending a fluid (blood) through a set of three cassettes 42 of the distribution section 40 to a centrifuge. The fluid is then brought or delivered to a second set of blood containers 62 via a vacuum that moves the fluid through a second set of three cassettes 42. Dennehey teaches a cassette bank having an odd number of cassettes, each having 1st and 2nd inlet ports allowing for bi-directional passage of fluid via separate chambers (Dennehey - col. 1 ll. 51-62, col. 2 ll. 36-48). A combination of Rosiello and Dennehey would require one set of three cassettes to provide separate blood pathways where treated fluid would be stored in a container other than the container the fluid originated from (Dennehey – col. 2 ll. 31-34). Rosiello i.v. of Dennehey as discussed would maintain the four-port junction of Rosiello, with distribution tubing connected at two locations opposite to one another, and the first inlet port of the cassette and the tubing from the container or blood bag, connected to the remaining connections of the port (Rosiello - col. 4 ll. 27-33). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Rosiello with Dennehey to provide a manageable blood processing system capable of processing multiple samples while having an odd number of cassettes, while maintaining a sterile pathway (Dennehey – col. 1 ll. 14-30).

8. Claims 5, 12, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosiello '742 and Dennehey '440 as applied to claims 1, 9, and 16 above, and further in view of Grim et al. 6,245,570. Rosiello i. v. of Dennehey as discussed would not provide for a bar code label on each of the incubation bags as taught by Grim '570, with element 40 shown on Figure

1. A bar code label 40 applied to an incubation bag or blood container of Rosiello i. v. of Dennehey would provide for a means to track the container and what it holds when used in conjunction with a computerized inventory system (col. 2 ll. 2-7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a bar code label of Grimm, on the blood containers and incubation bags of Rosiello i. v. of Dennehey as discussed, to provide a means for indexing the location, process, and substance associated with each container (Grimm col. 2 ll. 2-7).

9. Claims 6, 7, 14, and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosiello '742 and Dennehey '440 as applied to claim 1, 9, and 16 above, and further in view of Juji et al. 5,098,371. Rosiello i. v. of Dennehey as discussed does not teach a system having a four-port junction and where there are break-away closures on the working solution inlet tube and a second inlet tube as taught by Juji '371. Juji '371 teaches a break-way enclosure 51a in Figure 10 which provides a mechanism and sterile pathway for fluid to be transferred from one blood or fluid container to another while providing a means to disconnect any tubing associated with the pathway once the transfer is complete without loss of fluid or contamination of the system (Juji – col.2 ll. 18-36). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Juji with Rosiello i. v. of Dennehey as discussed, to provide break-away enclosures on the working solution inlet tube and second inlet tube to provide an operable and sterile means for making a connection or disconnection between containers (Juji col. 2 ll. 18-25, 40-46).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure and is listed on form 892 herewith.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard J. Weinstein whose telephone number is 571-272-9961. The examiner can normally be reached on Monday - Thursday 7:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ehud Gartenberg can be reached on 571-272-4828. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJW

12/05/06

EHUD GARTENBERG
SUPERVISORY PATENT EXAMINER